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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/560,181

12/09/2005

Gitte Juel Friis

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EXAMINER

FOLEY, SHANON A

ART UNIT

PAPER NUMBER

1619

MAIL DATE

DELIVERY MODE

05/27/2009

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/560,181	Applicant(s) FRIIS ET AL.	
	Examiner SHANON A. FOLEY	Art Unit 1619	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 22 May 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,3-15,19,20,27,28 and 30-35 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1, 3-15,19,20,27,28 and 30-35 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>6/16/2008</u> . | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

The Group and/or Art Unit of your application has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Group Art Unit 1619, Examiner Foley.

Applicant's arguments regarding the removability of Falk's wound care device persuasive. However, an updated search revealed pertinent references required to be made of record. Prosecution is being reopened.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1, 3, 4, 6, 7, 19, 20, 27, 28, 30 and 32-35 are rejected under 35 U.S.C. 102(e) as being anticipated by Cleary et al. (USPgPub 2003/0170308).

The claims are drawn to a wound care device in the form of a sheet-like layer [see paragraph 0138] for local (non-systemic) [see paragraphs 0017, 0047, 0166] treatment of pain comprising an active pain relieving agent of an NSAID or ibuprofen [see paragraph 0125] embedded or incorporated into a wound-contacting layer of hydrogel [see paragraphs 0119 and 0139] comprising nonstick petroleum resins [see paragraph 0065] that is suitable for permeability for wound exudates [see paragraphs 0018 and 0146]. The layer has a thickness between about 0.5 to 1.5 mm [see paragraph 0138], has a maximum absorption of 0.2 g/cm² [see

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line 3 of Table 6 on page 20], can be easily removed [see paragraph 0117] and additionally has an absorbent layer [see paragraph 0073]. Also see claims 1, 4, 56, 62 and 69-72.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claim 5 is rejected under 35 U.S.C. 103(a) as being unpatentable over Cleary et al. *supra*.

The instant claim states that the device has a maximum absorption rate of 0.05 g/cm².

See the teachings of Cleary et al. above. While Cleary et al. teach an absorption rate of 0.2 g/cm² in line 3 of Table 6 on page 20 for the hydrogel, Cleary et al. do not teach a maximum absorption rate of 0.05 g/cm². However, Cleary et al. also discuss the prior art disadvantage of adherence of absorbent material to wounds, rendering painful removal, see paragraphs [0003-0005]. Cleary et al. also discuss the hydrophobic materials that have limited absorptive capacity, see paragraph [0037] for example. Therefore, it would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to have modified the wound-covering material with a reasonable expectation of success for altering the amount of absorbency required for adequate protection and healing.

Claims 8-15 and 31 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cleary et al. *supra* and Edgren et al. (US 6,245,357).

The instant claims state that the release rate of the pain-relieving agent is at least 50, 75 or 90% during the first 6, 12 or 24 hours after application of the wound device.

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See the teachings of Cleary et al. above. Cleary et al. do not teach or suggest a release rate of pain-relieving agent.

However, Edgren et al. teach a release rate of an analgesic ranging between 55, 75 and 100% during the first 8, 12 and 24 hours after application of a , see claims 10, 46, 50, 51, 59 and 60.

One of ordinary skill in the art at the time the invention was made would have been motivated to alter the quantity of analgesic drug released from a wound device, depending on the severity of the wound and the duration for pain relief required. One of ordinary skill in the art at the time the invention was made would have had a reasonable expectation of success for altering the rate of analgesic release in the hydrogel of Cleary et al. in the wound care system of Edgren et al. since both wound care devices of both references use hydrogels to administer the pain-relief agents, see the previous citations of Cleary et al. and claims 28 and 36-38 of Edgren et al.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to SHANON A. FOLEY whose telephone number is (571)272-0898. The examiner can normally be reached on M-F 5:30 AM-3 PM, alternate Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael P. Woodward can be reached on (571) 272-8373. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Shanon A. Foley/
Primary Examiner
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